With diseases like anthrax, it is important to find an effective therapy quickly. Any delay can result in the death of a patient, or in the case of a larger exposure, in the deaths of thousands of individuals. If the U.S. and the rest of the world begin using Cipro haphazardly, that antibiotic could lose its effectiveness also.

□ 1245

To adequately prepare for a bioterrorist attack, State and local health departments must be equipped to rapidly identify and respond to antibiotic-resistant strains of anthrax and other lethal agents.

And to ensure the continued efficacy of our antibiotic stockpile, we must isolate emerging antibiotic-resistant pathogens, track antibiotic overuse and misuse, and monitor the effectiveness of existing treatments over time.

Surveillance also provides the data needed to prioritize the research and development of new antibiotic treatments.

Drug-resistant pathogens are already a growing threat to every American. Examples of important microbes that are rapidly developing resistance to available antimicrobials include the bacteria that cause pneumonia, ear infections, meningitis, and skin, bone, lung or bloodstream infections.

That list also includes food-borne infections like salmonella, and the Nation's food supply could be a future target of bioterrorism.

Under last year's Public Health Threats and Emergencies Act, sponsored by the gentleman from North Carolina (Mr. BURR) and the gentleman from Michigan (Mr. STUPAK), Congress authorized a grant program that would equip State and local health departments to identify and to track antibiotic resistance.

To build upon this already authorized program, the gentleman from New York (Mr. BOEHLERT) and I have asked the Committee on Appropriations to include at least $50 million for this grant program in the Homeland Security Supplemental Appropriations bill. I urge Members on both sides of the aisle to support that request.

Let our appropriators know that this funding is critical to the viability of our main weapons against bioterrorism and other infectious diseases now and in the future.

H.R. 2887, PEDIATRIC EXCLUSIVITY BILL

The SPEAKER pro tempore (Mr. CULBERSON). Under the Speaker's announced policy of January 3, 2001, the gentleman from Michigan (Mr. STUPAK) is recognized during morning hour debates for 5 minutes.

Mr. STUPAK. Mr. Speaker, I rise today to speak of a bill that may be coming to the floor in the very near future. It is called the H.R. 2887, the Pediatric Exclusivity bill. It was passed by Congress in 1997 to encourage drug companies to do studies in how their drugs would affect young people, those people under 18. Unfortunately, before this bill, drug companies did not necessarily take into consideration a drug's effect upon children 18 and younger, so Congress granted them a pediatric exclusivity which would allow them to extend their patent for another 6 months to do a study.

Now, when they get done with this study, what happens to the study? It goes to the FDA and sits there, but yet the drug company gets the extension of the patent.

From that study, we learned certain things, such as the dosage of medicine to be given and symptoms we should look for. What we found, since 1997, is that 33 drugs have been granted pediatric exclusivity. Of the 33, 20 of them have done label changes. The other 13 have not. Why not?

The problem we are concerned about is why we would grant pediatric exclusivity prior to receiving the study. We should wait and not grant pediatric exclusivity until after we have the study, we know what the dosage recommendation should be, and then the product is labeled for pediatric use according to the study. So what we want to see is that the grant of pediatric exclusivity is tied into not only a study but also the necessary label changes.

It only makes sense. The doctors, the patients, their families should know what was found in those studies and what they need to know to make sure that they are administering the drug in a proper way to young people.

The goal of pediatric exclusivity, the FDA has been quoted as saying, is the labeling. That is why when the bill comes to the floor we would like to offer an amendment which would tie the grant of exclusivity necessarily to labeling changes. As I said, there have been 33 pediatric exclusivity drugs, but only 20 of them have changed their labels. What about the last 13?

Currently, the exclusivity period is given only for doing a study. For the safety of our children, for the health care profession, and for all families, we should change this. Under our proposed amendment, all new drugs must complete the labeling requirement before the product is marketed.

I cannot understand why we allow drug manufacturers to undertake a pediatric study, but not provide parents and doctors with the results they need to make informed decisions to properly use and dispense the drugs. As the FDA says, the goal of pediatric exclusivity is labeling, and we cannot lose sight of that.

We went on the FDA Web site and they listed the drugs with the pediatric exclusivity. As seen on this chart, the first one, Lodine, Etodolac Lodine, 9 months after the pediatric exclusivity was granted, they changed their label. The labeling says it is now appropriate for young people 6 to 16, but the dose in younger children is approximately two times lower dosage than is recommended for adults.

Now, would the doctor not want to know that before he gives Lodine, since it is used for juvenile rheumatoid arthritis, that the recommended dose is two times less than what is given for adults? The manufacturer was granted the pediatric exclusivity on December 6, 1999, yet the information did not get out to the doctors and patients and their families until August.

Let us take this one right here. BuSpar. It was approved on May 22 this year for pediatric exclusivity. Two months later the labeling change comes out. And what did it find? The safety and effectiveness were not established in patients below the age of 18. In this drug here, they got the pediatric exclusivity, and 2 months later they had to change their label to let people know there really was no advantage. In fact, the safety and effectiveness was not established. I think that would give a red light to doctors and patients that maybe this drug is not doing what it is supposed to be doing.

This one on the bottom, the Propofol Diprivan. Take a look at it. It is for anesthesia. When we take a look at it, it says it may result in serious bradycardia. Propoful is not indicated for pediatric ICU sedation, as safety has not been established. Now, if I was a medical professional, I am sure I would want to know this.

Why does it take 18 months after the grant of the pediatric exclusivity to get the information out to the health care professionals?

If we look closer at this, the incidence of mortality, it is 9 percent versus 4 percent. So there is twice as much chance of a deadly accident occurring with this drug as when it was given in the old form. Again, it takes 18 months to get this information out.

So, again, before we grant pediatric exclusivity to a pharmaceutical such as this, should we not have the labeling change so we know what it is going to do to the patient, so the doctor knows what dosage he should recommend? That is the whole idea behind the labeling amendment. That is what we want to see be a part of the exclusivity bill.

It is a good bill, with good intent, but we have to finish the job. Now that we have had it on the books for 4 years, we have seen the shortfalls. So let us change the label so everybody is informed about the value of these drugs.

RECESS

The SPEAKER pro tempore. Pursuant to clause 12 of rule I, the Chair declares the House in recess until 2 p.m.

Accordingly (at 12 o'clock and 53 minutes p.m.), the House stood in recess until 2 p.m.

□ 1400

AFTER RECESS

The recess having expired, the House was called to order by the Speaker pro tempore (Mr. CULBERSON) at 2 p.m.